PATENT APPLICATION

THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of: Rapp et al.

Application No.: 10/031,851 Examiner: Yong Soo Chong

Filed: May 28, 2002 Docket No.: HMNZ 2 00021

For: USE OF TOSYLCHLORAMIDE(S) FOR TREATING DISEASES OF THE SKIN, MUCOUS MEMBRANE, ORGANS AND TISSUES

BRIEF ON APPEAL

Appeal from Group 1617

Karl W. Hauber Esq., Reg. No. 52,999
FAY SHARPE LLP
1228 Euclid Ave. – Fifth Floor
Cleveland, Ohio 44115
Telephone: (216) 363-9000
Attorneys for Appellant

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I. REAL PARTIES IN INTEREST

The real party in interest for this appeal and the present application is Engelhard Arzneimittel GmbH & Co. KG, Herzbegstrasse 3, D-61138 Niederdorfelden Germany, the assignee of the named inventors.

II. RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals or interferences.

III. STATUS OF CLAIMS

Claim 1 stands rejected. Claims 2-5 are canceled. Claims 6-21 stand rejected. Claims 22-33 are canceled. Claims 34-47 stand rejected.

The claims on appeal are claims 1, 6-21, and 34-47. A copy of these claims appears in the Appendix of Claims on Appeal attached hereto.

IV. STATUS OF AMENDMENTS

An amendment after final rejection was submitted on September 10, 2009. The amendment was not entered as noted in the Advisory Action of September 23, 2009.

The final Amendment, not entered, included an amendment to claim 46. Thus, the claims on appeal are as submitted on May 8, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claims on appeal recite Applicant's invention involving the use of tosylchloramides as effective substance for treating diseases of the skin, the mucous membranes, organs, and tissues. In particular, Applicant's invention teaches a method of topically treating efflorescent diseases of the skin and mucous membranes caused by herpes simplex virae. A pharmaceutical preparation is applied to the area to be treated wherein the preparation comprises alkali and/or alkaline earth salt of tosylchloramide and wherein the tosylchloramide salts are present in an employed base in an amount of approximately 0.1-20% by weight.

The subject matter of the present application is not a disinfectant or antiseptic treatment, but a treatment of a skin disease caused by herpes simplex virae. The claimed product has as active ingredients the sodium salt of tosylchloramide. A synonym of this salt is chloramine-T. The diseases to be treated are diseases of the skin and mucous membranes, and in particular, diseases caused by herpes simplex virae.

Applicant's invention involves the use of tosylchloramides as effective substance for treating diseases of the skin, the mucous membranes, organs, and tissues. In particular, Applicant's invention teaches a method of topically treating efflorescent diseases of the skin and mucous membranes caused by herpes simplex virae. A pharmaceutical preparation is applied to the area to be treated wherein the preparation comprises alkali and/or alkaline earth salt of tosylchloramide and wherein the tosylchloramide salts are present in an employed base in an amount of approximately 0.1-20% by weight.

The claims on appeal are claims 1, 6-21, and 34-47. Claims 1, 34, and 46 are independent. These claims are set forth below with references to specification passages providing support therein for the elements claimed.

1. A method of topically treating efflorescence diseases of the skin and mucous membrane (page 1, lines 1-2) caused by herpes simplex virae (page 1, lines 5-9), said method comprising the administration of a pharmaceutical preparation to the area to be treated of the alkali and/or alkaline earth salts of tosylchloramide (page 3, lines 1-12).

6. The method of Claim 1, characterized in that the diseases affect:

a) the lid, conjunctiva or cornea of the eye;
b) the exterior of the ear;
c) the nasal cavity;
d) the lips and mucous membranes of the mouth and/or the tongue;
e) the vulva and/or vagina;
f) the penis;
g) the anus;
h) the nail;
i) the hair follicles and/or the sebaceous glands; and/or
j) the hands and feet. (page 4, lines 1-9)

7. The method of Claim 1, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 0.1 to 20% by weight (page 4, lines 16-20).

8. The method of Claim 1, wherein sodium tosylchloramide salt is employed (page 4, lines 11-13).

9. The method of Claim 7, wherein said base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation (page 4, lines 20-24).

10. The method of Claim 9, wherein said base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick, a pulverized substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension (page 4, lines 20-24).

11. The method of Claim 9, wherein said base constitutes a dosed aerosol or a dosed solution (page 7, lines 7-9).

12. The method of Claim 9, wherein said base constitutes a bath water additive (page 5, lines 22-24).

13. The method of Claim 9, wherein said base is an O/W- or a W/O-emulsion ointment (page 5, lines 10-14).

14. The method of Claim 7, wherein said base is a cortisone-containing preparation (page 6, lines 16-18).

15. The method of Claim 9, wherein said base is a gel comprising said tosylchloramide salt(s), in an amount of approximately 0.1 to 5% by weight (page 4, lines 16-24).

16. The method of Claim 9, wherein a bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight (page 6, lines 22-26).

17. The method of Claim 1, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 5 to 15% by weight (page 4, lines 17-19).

18. The method of Claim 1, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 8 to 12% by weight (page 4, lines 16-19).

19. The method of Claim 9, wherein the base is a gel, in which are present said tosylchloramide salt(s), in an amount of approximately 0.1 to 2% by weight (page 4, lines 26-27).

20. The method of claim 1, further comprising a treatment schedule including an application duration from about 2 to about 20 days and an application frequency from about 1 to about 4 times per day (pages 13 & 14, table).

21. The method of claim 1, further comprising a treatment schedule including an application duration from about 2 to about 6 days and an application frequency from about 1 to about 3 times per day (pages 13 & 14, table).

Claims 22 – 33 (Cancelled)

34. A method of topically treating efflorescence diseases of the skin and mucous membranes (page 1, lines 1-2) caused by the herpes simplex virae (page 1, lines 5-9) comprising:

application of a pharmaceutically prepared medicament, to the area to be treated, having a salt of tosylchloramide selected from the group consisting of alkali salts, alkaline earth salts and mixtures thereof in an employed base in an amount of approximately 0.1 to 20% by weight.

35. The method of claim 34, wherein said base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation (page 4, lines 20-24).

36. The method of claim 35, wherein said base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick, a pulverized

substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension (page 4, lines 20-24).

37. The method of claim 35, wherein said base constitutes a dosed aerosol or a dosed solution (page 7, lines 7-9).

38. The method of claim 35, wherein said base constitutes a bath water additive (page 5, lines 22-24).

39. The method of claim 35, wherein said base is an O/W- or a W/O-emulsion ointment (page 5, lines 10-14).

40. The method of claim 34, wherein said base is a cortisone-containing preparation, containing said tosylchloramide salt(s), in an amount of approximately 0.1 to 20% by weight (page 6, lines 16-18).

41. The method of claim 35, wherein said base is a gel comprising said tosylchloramide salt(s), in an amount of approximately 0.1 to 5% by weight (page 4, lines 16-24).

42. The method of claim 35, wherein the bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight (page 6, lines 22-26).

43. The method of claim 34, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 5 to 15% by weight . (page 4, lines 17-19)

44. The method of claim 34, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 8 to 12% by weight (page 4, lines 16-19).

45. The method of claim 35, wherein the base is a gel, in which are present said tosylchloramide salt(s), in an amount of approximately 0.1 to 2% by weight (page 4, lines 26-27).

46. A method of topically treating efflorescence diseases of the skin and mucous membrane (page 1, lines 1-2) caused by herpes simplex virae (page 1, lines 5-9), said method comprising:

applying a pharmaceutical preparation to the area to be treated including alkali and/or alkaline earth salts of tosylchloramide (page 3, lines 1-12), wherein said tosylchloramide salts are present in an employed base in an amount of approximately 0.1 to 20% by weight; and, applying said preparation comprises a treatment schedule including an application duration from about 2 to about 20 days and an application frequency from about 1 to about 4 times per day (pages 13 and 14, Table).

47. The method of claim 46, wherein the base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation (page 4, lines 20-24).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

I. Claims 46-47 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

II. Claims 1, 3, 6-21, 34-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vandevelde et al. (WO 91/07876) in view of Berger (US PN 4,574,084).

III. Claims 1, 3, 6-21, 34-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Harwardt et al. (DE 41 37 544) in view of Berger.

VII. ARGUMENT

I. Claims 46-47 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection of those claims under 35 USC 112, second paragraph, as being indefinite, should be reversed.

REJECTIONS UNDER 35 U.S.C. §112

The Examiner stated that the limitation "pharmaceutical preparation to the area to be treated including alkali and/or alkaline earth salts of tosylchloramide" renders the claim indefinite as to whether the tosylchloramide is actually part of the pharmaceutical preparation or not. The Examiner suggested that Applicant use the conventional transition phrase "comprising" rather than "including" in order to show that the tosylchloramide is part of the pharmaceutical preparation.

Although Applicant did not use the conventional transition phrase "comprising", Applicant asserts that using the word "including" does show that the tosylchloramide is part of the pharmaceutical preparation.

The transitional term "comprising" is synonymous with "including", "containing", or "characterized by," which are all inclusive and/or open ended and do not exclude additional, unrecited elements or method steps. See e.g., *Mars Inc. v. H.J. Heinz Company, 377 F.3(d) 1369, 1376, 71 USPQ 2(d) 1837, 1843 (Fed. Cir. 2004).*

As such, Applicant asserts that the tosylchloramide is part of the pharmaceutical preparation and that claims 46-47 distinctly claim the subject matter which Applicant

regards as the invention.

II. Claims 1, 3, 6-21, 34-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vandevelde et al. (WO 91/07876) in view of Berger (US PN 4,574,084).

Applicant's invention involves the use of tosylchloramides as effective substance for treating diseases of the skin, the mucous membranes, organs, and tissues. In particular, Applicant's invention teaches a method of topically treating efflorescent diseases of the skin and mucous membranes caused by herpes simplex virae. A pharmaceutical preparation is applied to the area to be treated wherein the preparation comprises alkali and/or alkaline earth salt of tosylchloramide and wherein the tosylchloramide salts are present in an employed base in an amount of approximately 0.1-20% by weight.

The subject matter of the present application is not a disinfectant or antiseptic treatment, but a treatment of a skin disease caused by herpes simplex virae. The claimed product has as active ingredients the sodium salt of tosylchloramide. A synonym of this salt is chloramine-T. The diseases to be treated are diseases of the skin and mucous membranes, and in particular, diseases caused by herpes simplex virae.

Applicant's have amended the above listed claims to particularly point out that the method includes topically treating efflorescence diseases of the skin and mucous membranes caused by herpes simplex virae. The method comprises the administration of a pharmaceutical preparation to the area to be treated of the alkali and/or alkaline earth salts of tosylchloramide. Application of the pharmaceutically prepared

medicament to the area to be treated includes or comprises a medicament having a salt of tosylchloramide selected from the group consisting of alkali salts, alkaline earth salts, and mixtures thereof in an employed based in an amount of approximately 0.1-20% by weight.

The References

Berger merely teaches the preparation of a stabilized, modified, aqueous chlorite solution with a content of peroxide compound. The chlorite solution obtained by this process can be used in multiple ways as discussed hereinafter.

The only generalization one can make with Berger is that aqueous chlorite (a chlorine in oxidation state) solutions were already known and the invention now opens the possibility to use these chlorite solutions together with the stabilizing peroxy compounds in a broader manner. In column 7 starting from line 61 it is disclosed that the:

> "stabilized, modified chlorite solutions according to the invention also have further advantageous uses. Thus, it has been found than in particular dilute chlorite solutions according to the invention have excellent biocidal actions in the broadest sense. This more particularly applies to a dilute sodium chlorite, preferably with an approximately 0.1 to 0.5% by weight concentration".

The Examiner attempts to demonstrate that the generalization or broadening of the Berger reference is to use this particular teaching of a chlorite solution with the peroxide stabilizer used as a biocidal compound, provides the general teaching that skin diseases can be treated with any biocidal composition used for disinfection.

To the contrary, Berger does not teach that any kind of biocidal composition can be used for the treatment of skin diseases. Berger specifically states that "the agent according to the invention and particularly the sodium chlorite solution can also be used for treating skin diseases . . ." (column 8, lines 9-11).

When studying Berger in "Technical Field", it is clear that the invention discloses and concerns a process for the preparation of a stabilized modified aqueous chlorite solution with a content of a peroxy compound.

To broaden this teaching in a sense that salts of tosylchloramide can be used to treat efflorescent diseases of the skin and mucous membrane caused by herpes simplex virae is not correct.

The uses of tosylchloramide disclosed in Berger are only disclosed in connection with a peroxide stabilized solution.

To illustrate that there is no general teaching of a nexus between skin diseases and biocidal compositions that are used for disinfection, Applicant had previously submitted (May 8, 2009) the enclosed Technical Data Bulletin, (Evidence Appendix) for PERMA-WASH disinfectant describes a combination of chlorine dioxide (an oxide of chlorine) which "produces a highly potent broad spectrum biocide concentrate". This combination is useful as a broad spectrum disinfectant for HIV and Herpes Simplex Virus on inanimate environmental surfaces.

While the biocide of PERMA-WASH can disinfect inanimate objects, it also includes a CAUTION to "avoid contact with skin, eyes, or clothing". The first aid instructions include rinsing skin immediately with plenty of water for 15-20 minutes and to call a poison control center or doctor for treatment advice.

In contrast to the Examiner's assertion, as illustrated above, Berger does not provide the "general teaching" that skin diseases can be treated with biocidal compositions that are used for disinfection. With reference to the PERMA-WASH product, just the opposite is taught. Thus, one of ordinary skill in the art would not have had a reasonable expectation of success in treating skin diseases using a composition comprising tosylchloramide.

Therefore, Berger does not teach a nexus between skin diseases and biocidal compositions that are used for disinfection. Berger can be used only for the limited teaching of the particular composition described in Berger, i.e. a dilute sodium chlorite solution according to the particulars described therein.

Therefore, any teaching given by Berger cannot be transferred to the particular compounds and methods now recited in independent claims 1, 34 and 46 of the present application.

The active ingredients of Vandevelde which can contain chloramine-T are described for disinfection matters only. There is absolutely no indication in Vandevelde that chloramine-T is suitable for the topical treatment of efflorescence skin diseases, much less herpes simplex virae.

The examiner acknowledges that Vandevelde does not expressly disclose the employment of tosylchloramide in methods of the particular skin diseases herein

and since Berger does not provide the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection; one of ordinary skill in the art would not have had a reasonable expectation of success in treating skin diseases caused by Herpes Simplex virae as recited in the present application.

We are of the opinion, that the Examiner makes an inadmissible interpretation of the prior art documents.

The Examiner makes generalizations in documents which do not state tosylchloramide salts but state only disinfections in a sense that disinfections in general can be used as pharmaceutical for treating skin diseases.

A disinfecting agent is an agent with a strong effect of killing all of the possible bacteria, fungi, viruses etc., in the sense of an over-killing function to assure that none of the bacteria, fungi, viruses, etc. will survive a treatment.

One skilled in the art would not envisage to use a disinfectant for topically treating efflorescent diseases of the skin or mucous membrane caused by herpes simplex virae.

A second inadmissible step, from our view, is that the Examiner picks up documents describing the effect of tosylchloramide salts in connection with other compounds but not tosylchloramide salts alone and he interprets this as an indication to use salts of tosylchloramide as such.

In the prior art documents the use of tosylchloramide salts is described to enhance or to assist other ingredients. From our view there is no teaching that alkali salts of tosylchloramide as such show the effects as stated by the Examiner. The Examiner makes an inadmissible combination of these generalized or picked out items.

If the aforementioned path of argumentation would be admissible, one could kill every patent application in the field of pharmacy or chemistry if there is anywhere described a compound as such and in another document what such compounds can be used for.

Applicant considers the interpretation of Vandevelde as done by the Examiner inappropriate.

Vandevelde clearly discloses to use chloramines T as a strong disinfection for treating in particular, HIV viruses which were released by people prior to a death caused by these viruses.

One skilled in the art clearly takes the teaching from Vandevelde that beds, toilets, rooms, closets, furniture, which were in contact with such people prior to death must be treated with an extremely strong agent which releases chlorine for killing all of these viruses.

In World War I, during gas attacks for killing soldiers, gases were used which released chlorine. If one follows the argumentation of the Examiner, this would stimulate an expert to use chlorine as a pharmaceutical to treat skin diseases.

Combination of Vandevelde and Berger

Contrary to the Examiner's assertion, applicant is not attacking the references individually, but rather, the Applicant is demonstrating that each reference does not show what the Examiner asserts and thus the combination of the references, in turn, cannot show what the Examiner asserts.

The Examiner asserts that Berger "discloses the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. Furthermore, these skin diseases can be effectively treated with biocidal compositions that are used for disinfection". The Examiner then discounts Applicant's arguments that Berger does not teach that skin diseases can be treated with any biocidal composition used for disinfection.

The Examiner comments, in response to Applicant's arguments, that the Berger reference was "used to show the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. In this manner, the Berger reference was not relied on for any teaching of therapeutically active agents". In this manner, the Examiner responds to Applicant's arguments regarding Berger and comments that Berger has only been used to show the general teaching that common inflammatory skin diseases are caused by bacteria, viruses, and fungi.

If the general teaching of Berger is merely to show that common inflammatory skin diseases are caused by bacteria, viruses and fungi, then the Examiner has not demonstrated a prima facie case of obviousness. The Examiner here argues that the Berger reference was not relied on for any teaching of therapeutically active agents. Thus, a prima facie case of obviousness has not been established because the combination of Vandevelde et al. and Berger does not make obvious Applicant's claims.

But, contrary to that assertion, the Examiner has stated in multiple occurrences that Berger is relied on for showing not only that common inflammatory skin diseases are caused by bacteria, viruses, and fungi, but also that skin diseases can be effectively treated with biocidal compositions that are used for disinfection. If the latter is the

argument that the Examiner is relying upon, Applicant has argued and continues to argue that this latter assertion is not accurate. Namely, Berger does not provide the general teaching that skin diseases can be treated with any biocidal composition used for disinfection. Applicant tried to demonstrate in its previous responses, including an exhibit, that biocidal compositions that are used for disinfection are not necessarily suitable for treating skin diseases. Quite the opposite is found. In particular, many biocidal compositions are possible for disinfection, but contact must be avoided with the skin, eyes, etc. The date of publication of the previously filed exhibit is not pertinent to this argument. Applicant was merely demonstrating one such example where a biocidal composition should not and cannot be used for treating skin diseases. There are many other examples that Applicant can provide. Applicant is merely trying to rebut the Examiner's assertion that Berger provides a general teaching that skin diseases can be treated with <u>any biocidal composition</u>.

In Applicant's previous responses, where Applicant has tried to make the aforementioned argument, the Examiner then states that Berger is merely relied upon for the general teaching that common inflammatory skin diseases are caused by bacteria, viruses, and fungi. The Examiner appears to advance differing arguments regarding the teachings found in Berger. The Examiner presents a confusing and contradictory assessment of the Berger reference and has presented a difficult circumstance for Applicant to argue what the reference does or does not show. Again, Applicant is not trying to attack the references individually, but rather is trying to assert what each reference teaches. Thus, once the teachings have been identified, the combination of these references can then be ascertained. In light of the above, Applicant contends that Berger does not provide the general teaching that common skin

diseases such as psoriasis and herpes can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill would not have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition as disclosed by Vandevelde et al.

Further, as discussed above, if the general teaching in Berger is only that skin diseases are caused by bacteria, viruses, and fungi, then the prima facie case of obviousness has not been established, thus the combination of Berger and Vandevelde et al. does not make obvious Applicant's claims.

On the other hand, if Berger is being used to disclose the general teaching that skin diseases can be effectively treated by biocidal compositions that are used for disinfection, then Applicant has legitimately countered that assertion by demonstrating that Berger does not provide the general teaching that skin diseases can be effectively treated with any biocidal composition that is used for disinfection. The latter general teaching has not been demonstrated by Berger and is not supported by evidence in the field of disinfection. Many biocidal compositions that are used for disinfection are harmful and dangerous to any contact with the skin or eyes and are extremely detrimental to any type of skin contact or for any type of treatment for skin diseases.

Furthermore, the Examiner asserts that Vandevelde clearly teaches tosylchloramides, and its known derivatives, can be used for topical administration to skin broadly and hair and can be used in methods of treating skin diseases. The Examiner further states that "the mere mention that chloramine-T acts against viruses on inanimate objects provides sufficient motivation to administer a composition comprising chloramine-T as a medicament or a pharmaceutical composition for treating other skin diseases". This statement is merely a conclusory statement not supported by

any evidence, nor is it supported by any references cited by the Examiner. To the contrary, any mention that a particular compound can act against a virus on an inanimate object does not alone provide sufficient motivation to administer the same composition for treating skin diseases. As discussed above, many disinfectants, used for inanimate objects, cannot and should not be used for topical treatment of skin diseases. Many disinfectants are extremely dangerous and detrimental to any type of skin contact. One can not merely assert that any disinfectant used for disinfecting inanimate objects provides sufficient motivation to administer the same composition for treating skin diseases. That statement is not supported by the evidence in the record nor is it supported by the knowledge of one skilled in the art.

None of the cited references, either singularly or in combination, provide any teachings for addressing the problems addressed by the present application. There is no suggestion, motivation, or teaching to combine the references. There is no motivation to combine the cited references to modify their teachings to reach the above referenced claims. "The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious". *United States v. Adams*, 383 U.S. 39, 51-52 (1966); and cited with approval in *KSR Int'l v. Teleflex*, Inc., 127 S. Ct. 1727, 1740-1741 (2007).

Although taught away from, if one combines the teaching of Berger with Vandevelde one may add to the tosylchloramide-T compound of Vandevelde additionally a peroxide of Berger to stabilize this compound for the purpose of disinfection. If one starts from Vandevelde, one comes to the same conclusion, i.e. to

combine for disinfection purposes the chloramine-T with additional stabilizing peroxide compounds for disinfecting HIV contaminated dead bodies.

However, in each scenario one does not arrive at the method recited in claims 1, 34, and 46.

Applicant submits that there is no suggestion to combine the teachings and suggestions of Vandevelde and Berger, as advanced by the Examiner, except for using Applicant's disclosure as a template through a hindsight reconstruction of Applicant's claims.

III. Claims 1, 3, 6-21, and 34-47 were rejected under 35 U.S.C 103(a) as being unpatentable over Harwardt et al. in view of Berger.

Combination of Harwardt [Kramer] and Berger

The examiner acknowledges that Harwardt et al. does not expressly disclose the employment of tosylchloramide in methods of the particular skin diseases herein, and since Berger does not provide the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection; one of ordinary skill in the art would not have had a reasonable expectation of success in treating skin diseases caused by herpes simplex virae as recited in Applicant's claims.

The arguments raised with respect to Vandevelde and Berger are appropriate here and will not be repeated. Combining the references is not suggested and is particularly taught away from.

Again, the Examiner appears to rely on Berger for teaching that common skin diseases are caused by bacteria, viruses, and fungi, and also that Berger provides the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Applicant has countered the Examiner's assertions as discussed in detail above. The Examiner concludes that "one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide as disclosed by Harwardt et al. because of the beneficial therapeutic effects of tosylchloramides on killing and destroying harmful microorganisms that cause such skin diseases".

The Examiner's conclusory statement is not supported by the evidence nor is it supported by the combination of Harwardt and Berger as discussed in detail above. The Examiner expressly states "Harwardt et al. does not expressly disclose the employment of tosylchlramides in methods of the particular skin diseases herein" but later states that, because of Harwardt et al., the beneficial therapeutic effects of tosylchloramides on killing and destroying harmful microorganisms that cause such skin diseases is somehow disclosed. Again, Applicant finds it difficult to counter the assertions of the Examiner as arguments and observations of the cited references are altered and described in conclusory statements rather than by supported evidence in the record.

The Examiner attempts to demonstrate that the generalization or broadening of the Berger reference is to use a particular teaching of a chlorite solution with a peroxide stabilizer used as a biocidal compound, provides the general teaching that skin diseases can be treated with any biocidal composition used for disinfection.

To the contrary, Berger does not teach that any kind of biocidal composition can be used for the treatment of skin diseases. Berger specifically states that "the agent according to the invention and particularly the sodium chlorite solution can also be used for treating skin diseases . . ." (column 8, lines 9-11).

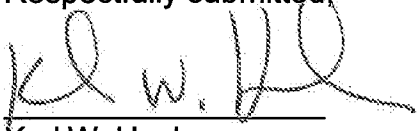
None of the cited references, either singularly or in combination, provide any teachings for addressing the problems as identified by Applicant. There is no motivation to combine any of the cited references to modify their teachings to reach the above referenced claims.

Combining the cited references would not result in Applicant's claimed invention as recited above. In effect, the combination of references stated in the office action is being assembled to address the problem Applicant is addressing by the method described by Applicant. Consequently, independent claims 1, 34 and 46, and all claims dependent therefrom, define over any fair teachings attributable to the references either taken singularly or in combination.

CONCLUSION

For all of the reasons discussed above, it is respectfully submitted that the rejections are in error and that claims on appeal are in condition for allowance. For all of the above reasons, Appellants respectfully request this Honorable Board to reverse the rejections of claims 1, 6-21, and 34-47.

Respectfully submitted,



Karl W. Hauber
Registration No. 52,999

FAY SHARPE LLP
1228 Euclid Avenue – Fifth Floor
Cleveland, Ohio 44115

Telephone: (216) 363-9000

Filed: March 15, 2010

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APPENDICES

VIII. CLAIMS APPENDIX

Claims involved in the Appeal are as follows:

LISTING OF THE CLAIMS

1. A method of topically treating efflorescence diseases of the skin and mucous membrane caused by herpes simplex virae, said method comprising the administration of a pharmaceutical preparation to the area to be treated of the alkali and/or alkaline earth salts of tosylchloramide.

6. The method of Claim 1, characterized in that the diseases affect:
   a) the lid, conjunctiva or cornea of the eye;
   b) the exterior of the ear;
   c) the nasal cavity;
   d) the lips and mucous membranes of the mouth and/or the tongue;
   e) the vulva and/or vagina;
   f) the penis;
   g) the anus;
   h) the nail;
   i) the hair follicles and/or the sebaceous glands; and/or
   j) the hands and feet.

7. The method of Claim 1, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 0.1 to 20% by weight.

8. The method of Claim 1, wherein sodium tosylchloramide salt is employed.

9. The method of Claim 7, wherein said base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.

10. The method of Claim 9, wherein said base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick, a pulverized substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension.

11. The method of Claim 9, wherein said base constitutes a dosed aerosol or a dosed solution.

12. The method of Claim 9, wherein said base constitutes a bath water additive.

13. The method of Claim 9, wherein said base is an O/W- or a W/O-emulsion ointment.

14. The method of Claim 7, wherein said base is a cortisone-containing preparation.

15. The method of Claim 9, wherein said base is a gel comprising said tosylchloramide salt(s), in an amount of approximately 0.1 to 5% by weight.

16. The method of Claim 9, wherein a bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight.

17. The method of Claim 1, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 5 to 15% by weight.

18. The method of Claim 1, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 8 to 12% by weight.

19. The method of Claim 9, wherein the base is a gel, in which are present said tosylchloramide salt(s), in an amount of approximately 0.1 to 2% by weight.

20. The method of claim 1, further comprising a treatment schedule including an application duration from about 2 to about 20 days and an application frequency from about 1 to about 4 times per day.

21. The method of claim 1, further comprising a treatment schedule including an application duration from about 2 to about 6 days and an application frequency from about 1 to about 3 times per day.

34. A method of topically treating efflorescence diseases of the skin and mucous membranes caused by the herpes simplex virae comprising:

application of a pharmaceutically prepared medicament, to the area to be treated, having a salt of tosylchloramide selected from the group consisting of alkali salts, alkaline earth salts and mixtures thereof in an employed base in an amount of approximately 0.1 to 20% by weight.

35. The method of claim 34, wherein said base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.

36. The method of claim 35, wherein said base constitutes an ointment, a gel, a cream, a paste, a suppository, such as a vaginal suppository, an adhesive bandage, a tablet, such an effervescent or vaginal tablet, or a capsule, a stick, a pulverized substance, a powder, a solution, an aerosol, a two-compartment system or a suspension, such as a shake mixture/dry suspension.

37. The method of claim 35, wherein said base constitutes a dosed aerosol or a dosed solution.

38. The method of claim 35, wherein said base constitutes a bath water additive.

39. The method of claim 35, wherein said base is an O/W- or a W/O-emulsion ointment.

40. The method of claim 34, wherein said base is a cortisone-containing preparation, containing said tosylchloramide salt(s), in an amount of approximately 0.1 to 20% by weight.

41. The method of claim 35, wherein said base is a gel comprising said tosylchloramide salt(s), in an amount of approximately 0.1 to 5% by weight.

42. The method of claim 35, wherein the bath water additive is employed in form of pulverized substance or bath salt tablet or effervescent tablet, which is applied in water in a concentration of approximately 0.1 to 1% by weight.

43. The method of claim 34, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 5 to 15% by weight.

44. The method of claim 34, wherein said tosylchloramide salt(s), are present in an employed base in an amount of approximately 8 to 12% by weight.

45. The method of claim 35, wherein the base is a gel, in which are present said tosylchloramide salt(s), in an amount of approximately 0.1 to 2% by weight.

46. A method of topically treating efflorescence diseases of the skin and mucous membrane caused by herpes simplex virae, said method comprising:

applying a pharmaceutical preparation to the area to be treated including alkali and/or alkaline earth salts of tosylchloramide, wherein said tosylchloramide salts are present in an employed base in an amount of approximately 0.1 to 20% by weight; and, applying said preparation comprises a treatment schedule including an application duration from about 2 to about 20 days and an application frequency from about 1 to about 4 times per day.

47. The method of claim 46, wherein the base constitutes a liquid, semi-solid or solid, water-containing or water-free galenic preparation.

IX. EVIDENCE APPENDIX

Exhibit A was submitted with Amendment filed on May 8, 2009, and the Evidence was entered into the record by the Examiner in the Office Action of July 28, 2009.

A copy of each of the following items of Evidence relied on by the Appellant is enclosed:

X. RELATED PROCEEDINGS APPENDIX

NONE

EXHIBIT A

ZINSSER
QUALITY SINCE 1849

Technical Data Bulletin

ZINSSER Co., Inc.
173 Belmont Drive, Somerset NJ 08875 An RPM Company

1/06

PERMA-WASH™

DISINFECTANT & FUNGICIDE INTERIOR CONCENTRATE

PERMA-WASH™ Disinfectant and Fungicide Interior Concentrate is a disinfectant, fungicide, virucide*, bactericide, mildewcide and mildewstat. It also provides exceptional cleaning and deodorizing. PERMA-WASH™ has broad-spectrum efficiency and economy for commercial, institutional and industrial disinfection in hospitals, medical and dental offices, nursing homes, industrial and institutional facilities.

PERMA-WASH™ is EPA registered for mold & mildew control on hard surfaces in Hospitals, Institutions, and Homes. Its fast mode of action makes it the perfect product for effective single operation mold & mildew control. The ability of PERMA-WASH™ to counteract and oxidize odors offers a definite plus to its disinfecting activity.

Selection Data

Generic Type – Unique Cryocide® Disinfectant Brand technology - A combination of Chlorine Dioxide, Quaternary Ammonia, and surfactant that produces a highly potent broad spectrum biocide concentrate that is less damaging than household bleach – lower odor; less corrosive; and it won't discolor.

EPA Data –EPA Reg. No. 9150-11-71240. NOTE: IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Performance Characteristics

- **Fast mode of action** – it works rapidly and thoroughly to control mold & mildew on hard surfaces in a single treatment.
- **Odor counteractant** – oxidizes malodors. Provides exceptional cleaning and deodorizing without the damage or discoloration that bleach can cause.
- **Disinfectant, fungicide, virucide*, bactericide, mildewcide and mildewstat** – broad-spectrum efficiency and economy for commercial, institutional & industrial disinfection. *Human Immunodeficiency Virus Type 1 (HIV-1)(AIDS Virus) • Herpes Simplex Virus Type 1 and 2 • Influenza A2 (Hong Kong-68) Virus on Inanimate Environmental Surfaces.

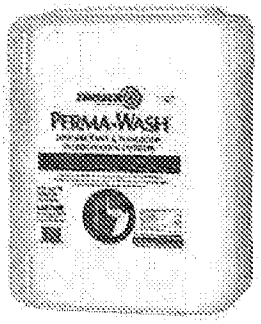
Recommended Uses – PERMA-WASH™ is recommended for use on hard, non-porous surfaces such as walls, floors, basins, bathroom fixtures, sinks, bathtubs, chairs, counter-tops, tables, sinks, toilets, urinals and other hard, non-porous surfaces.

PERMA-WASH™ can be topcoated with any latex, alkyd, or shellac base clear or pigmented paint or coating. It will not damage (cured) paint films making it excellent for maintenance. (Follow label dilution directions. Pretest painted surfaces for color retention).

Application Data

Mixing instructions- **For treating mold and mildews:** A gallon of **PERMA-WASH™** makes 5 gallons of solution; five gallons of PERMA-WASH™ makes 25 gallons. Actual coverage will depend upon quantity applied and porosity of the surface.

To Treat Surfaces Contaminated With Mold & Mildew



1. Mix 1 part PERMA-WASH™ Concentrate with 4 parts water.
2. Remove all heavy build-up of gross filth and loose debris from areas to be treated. To reduce spore spread, pre-treat with PERMA-WASH™. Wait 10 minutes.
3. After heavy debris is removed, re-apply PERMA-WASH™.

Application: Use a commercial low-pressure sprayer 6 to 8 inches from the surface or use a mop, sponge, wipe or other suitable device.

Note: Where mist or vapors may be generated, proper ventilation must be provided in accordance with good ventilation practices. In the absence of proper environmental controls, a NIOSH approved respirator is advised.

4. Make sure the treated area is thoroughly wet for at least 10 minutes and allow to air dry. Remove any mold debris remnants.
5. Repeat every 7 days or more frequently if growth reoccurs.

NOTE: Since dead mold spores – even those turned white or invisible by bleaching – can be a food source for future mold growth, it is essential that even dead mold be removed by cleaning or scrubbing. PERMA-WASH™ works rapidly on mold spores while allowing for effective visual removal of any remaining mold debris.

For Preventative Maintenance Against Mold & Mildew

1. Mix 1 part PERMA-WASH™ Concentrate with 7 parts of water.
2. Follow Steps 2 – 4 listed above.
3. Repeat application at weekly intervals or when growth appears.

Hospitals, Medical and Dental Offices, Nursing Homes Disinfection & Virucidal (against HIV-1, Herpes Simplex and Influenza): Use undiluted (neat) Apply undiluted PERMA-WASH™ to hard, non-porous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer, or by immersion. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For heavily soiled surfaces, a pre-cleaning is recommended. **Rinse all surfaces that come in contact with foods such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.** For sprayer applications, use a coarse spray device. Spray 6 to 8 inches from the surface rub with a brush, sponge or cloth. Do not breathe spray. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body,

Either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi critical medical devices prior to sterilization or high-level disinfection.

***SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV OR SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS** that involve healthcare settings or other settings in which there is an unexpected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects soiled with blood or body fluids can be associated with the transmission of HIV-1. PERMA-WASH™ Disinfectant and Fungicide destroys HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood or other body fluids in 30 seconds contact.

Personal Protection: The worker should wear disposable latex gloves or rubber gloves, gown, mask and eye protection to prevent contamination from soiled items.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of PERMA-WASH™ Disinfectant and Fungicide Interior Concentrate.

Contact Time: Allow PERMA-WASH™ Disinfectant and Fungicide to contact treated items for 30 seconds. This time will not control other common types of viruses and bacteria.

Disposal of Infectious Material: Any blood or other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

Shelf Life	12 months from date stamp
Storage/Handling	Store indoors 40°F – 80°F Keep away from extreme heat.

IMPORTANT NOTE:
EPA Reg. No. 9150-11-71240
(Not available for sale in California).

Limited Warranty

This product will perform as claimed when used according to label directions. Directions are as complete as possible but cannot encompass all conditions, applications, and/or surfaces beyond manufacturer's control. The contents are warranted to be free of defects for one year from date of manufacture. All warranties and guarantees are limited to replacement or refunded value of product actually used when supported by proof of purchase. This guarantee is not transferable. If you have a question, check with your dealer or call ZINSSER CO., Inc.

PRECAUTIONARY STATEMENTS: Hazards to Human & Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with skin eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in the original container in a dry, temperature controlled area. Do not store in a manner where cross-contamination with other pesticides, fertilizers, food or feed could occur. If spilled during storage or handling, contain/recapture spillage and dispose of in accordance with the Pesticide Disposal Instructions listed below.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Cryocide® is a registered trademark of International Dioxide, a Dupont Company.

Packaging and Shipping Information

Unit Size	Code	Product UPC	Carton Code	Harmonized/ HazmatCode	Case Pack	Case Wt. Lbs.	Dimensions	Case Vol. Inches	Pallet Pack	Pallet Size
1 gallon	60601	0 47719 60601 7	4 00 47719 60601 5	3808.30.0000	4	38	14 " x 7 1/2" x 10 1/2"	1,102	144	42 x 42
5 gallon	60600	0 47719 60600 0	N/A	Non Haz-Fung	1	43.0	12 3/4" x 9" x 13"	1,492	36	42 x 42